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IN THE

Supreme Court of the United States

October Term, [redacted] 1970

No. [redacted] 263

BRISTOL-MYERS COMPANY,

Petitioner,

v.

FEDERAL TRADE COMMISSION, PAUL RAND DIXON, A. EVERETTE MACINTYRE, PHILIP ELMAN, JOHN R. REILLY and MARY GARDINER JONES, as Commissioners of The Federal Trade Commission.

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

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June, 1970

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No.

BRISTOL-MYERS COMPANY,

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v.

FEDERAL TRADE COMMISSION, *et al.*

PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE DISTRICT OF COLUMBIA CIRCUIT

Petitioner prays that a writ of certiorari issue to review the judgment of the United States Court of Appeals for the District of Columbia Circuit, entered on March 26, 1970, insofar as it affirms the order of the District Court granting the motion to dismiss the second, third, fourth and fifth causes of action in the complaint.

Opinions Below

The opinion of the District Court is printed in Appendix I, *infra*, page 1a, and is reported at 284 F. Supp. 745. The opinion of the Court of Appeals is printed in Appendix I, *infra*, page 9a, and is not yet reported.

Jurisdiction

The judgment of the Court of Appeals was dated and entered March 26, 1970 (Appendix I, *infra*, page 16a). The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1).

Questions Presented

1. Whether the Federal Trade Commission's Procedures and Rules of Practice § 1.12, 16 C.F.R. § 1.12, purportedly authorizing itself via non-adjudicative process to enact trade regulation rules which it may subsequently rely upon to resolve "any issue involved in an adjudicative proceeding" is a regulation *ultra vires*, particularly in light of section 5(b) of Federal Trade Commission Act, 15 U.S.C. § 45(b), and sections 5(d), 6(d), 7(c)(2)(4), 7(d) and 7(e) of the Administrative Procedure Act, 5 U.S.C. §§ 554(d), 555(d), 556(c)(2)(4), 556(d) and 556(e), respectively, and the due process clause of the Fifth Amendment to the Constitution of the United States; and, hence, whether the Commission's proceeding, based and dependent upon § 1.12, to promulgate "a Trade Regulation Rule regarding unfair and deceptive acts or practices in the advertising of nonprescription systemic analgesic drugs" (Appendix II, *infra*, pages 27a-31a) is a valid proceeding.

2. Whether petitioner is entitled at this time to have judicial review of the validity of § 1.12 and of the Commission's offshoot proceeding to promulgate the trade regulation rule referred to above on either of the following grounds:

a. That § 1.12 is a "final agency action" within the meaning of section 10(c) of the Administrative Procedure Act, 5 U.S.C. § 704, which confers a ripe right to judicial review of such actions; or

b. That petitioner's demonstratedly immediate, substantial and irreparable injury, which has been caused, and which will be caused by mere further pursuance of the above-described trade regulation rulemaking proceeding even if no rule were promul-

gated as a result thereof, allows judicial intervention at this, the only time it can be meaningful and effective.

Constitutional, Statutory and Rules Provisions Involved

This case involves the following provisions which are reprinted in pertinent part in Appendix II, *infra*, pages 17a-31a:

1. United States Constitution, Amendment V (*infra*, page 17a).

2. Sections 5(a)(1), 5(a)(6), 5(b), 6(g) and 9 of the Federal Trade Commission Act, 15 U.S.C. §§ 45(a)(1), 45(a)(6), 45(b), 46(g), and 49 (*infra*, pages 17a-19a).

3. Sections 2(4), 2(13), 4(b)(2), 5(d), 6(b), 6(d), 7(c)(2)(4), 7(d), 7(e), 10(c) and 12 of the Administrative Procedure Act, 5 U.S.C. §§ 551(4), 551(13), 553(b)(2), 554(d), 555(b), 555(d), 556(c)(2)(4), 556(d), 556(e), 704 and 559 (*infra*, pages 19a-22a).

4. Declaratory Judgment Act, 28 U.S.C. § 2201 (*infra*, page 23a).

5. Sections 1.12, 3.31-3.34, 3.41(c), 3.42(f), 3.43(a), 3.43(b) and 4.7 of the Procedures and Rules of Practice for the Federal Trade Commission, 16 C.F.R. §§ 1.12, 3.31-3.34, 3.41(c), 3.42(f), 3.43(a), 3.43(b) and 4.7 (*infra*, pages 23a-27a).

6. 32 Fed. Reg. 9843 (*infra*, pages 27a-31a).

Statement

On July 16, 1967, the Federal Trade Commission (hereafter the "Commission") initiated, by notice in the Federal Register, a rulemaking proceeding for the promulga-

tion of a trade regulation rule relating to the advertising of nonprescription analgesic drugs (27a-31a). The specific authority cited for such proceeding was Part I, Subpart B of the Commission's Procedures and Rules of Practice (27a), the pertinent portion of which would be embraced in § 1.12 relating to trade regulation rules (23a-24a).

Section 1.12(c) assumes a power in the Commission to use trade regulation rules, which the Commission promulgates by rulemaking rather than by adjudicative proceedings, to resolve "any issue involved in an adjudicative proceeding thereafter instituted".

The proposed trade regulation rule here at issue would resolve issues of fact otherwise triable in adjudicative proceedings, and would also enact substantive rules of law not otherwise established by statute or common law, to wit:

- It would make unlawful *per se* advertising claims that a particular analgesic product is qualitatively superior to competing products in speed, strength, or duration, regardless of whether such factual representations are, in fact, unfair or deceptive (29a).

- It would make advertising claims for efficacy or safety of an analgesic product unlawful *per se* if in any manner they contradict or exceed what appears in its labeling, regardless of whether such representations are, in fact, unfair or deceptive (29a).

- It would make any advertising claims that a specified ingredient or combination of ingredients will produce a benefit to the user of a particular analgesic unlawful *per se* unless the ingredient or combination of ingredients intended is clearly and conspicuously disclosed by its common or usual name, regardless of whether the representation is, in fact, unfair or deceptive by virtue of failure so to disclose (29a).

The Commission publicly announced its proposed trade regulation rule to be one "regarding unfair and deceptive acts or practices in the advertising of nonprescription systemic analgesic drugs", and continued:

> "The Commission has initiated this proceeding, having reason to believe that manufacturers and other marketers of nonprescription systemic analgesic drug preparations, in the advertising of such products, have: (1) * * *; (2) falsely and deceptively represented that the analgesic effects resulting from the use of their products are faster, stronger, or longer lasting than those achieved by use of such competing products. (It appears that each of the various analgesic products now offered to the consuming public is effective to essentially the same degree as all other competing products supplying an equivalent quantity of an analgesic ingredient or combination of ingredients); (3) * * *; (4) * * *; and therefore, that (5) these practices constitute an unfair method of competition and an unfair deceptive act or practice, in violation of sections 5 and 12 of the Federal Trade Commission Act". (28a.)

The Commission's press release publicizing the rule-making proceeding stated that its purpose was "to prevent deceptive advertising of nonprescription analgesic drugs", and went on to emphasize that "Targets of the proposed rule are the following unfair and deceptive advertising practices which the Commission has reason to believe *are being used by marketers of these over-the-counter analgesics* * * *. In initiating this proceeding, the Commission pointed out that one of its prime duties is protecting 'the consuming public from *false, misleading, deceptive,* or *unfair* advertising of products, *particularly those that may endanger human health or safety*'." (A-102-A-103[1]; emphasis added.)

Reverberant publicity was immediately generated depicting petitioner as having been found by the Commission to be a major perpertrator of false and deceptive advertis-

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[1] Pages designated with the letter A are from APPENDIX TO BRIEFS printed for use in the Court of Appeals and which has been included in the transcript of the record accompanying this petition.

ing referred to in the Commission's above announcement and press release (A-16-A-18).[2]

Petitioner, being a leading manufacturer and advertiser of drugs which would be seriously affected by the proposed rule and the foreseeable victim of further harmful adverse publicity attendant upon additional public proceedings by the Commission regarding it, sought to protect its interests and its image to the extent possible by petitioning the Commission, among other things, to allow it an opportunity to depose persons, supposedly expert, whose views would be used in support of the proposed rule; whether as witnesses in person or as authors of writings which would be made part of the public record for that purpose. Petitioner also prayed that further public proceedings be postponed until that had been done. (A-41-A-48; see also A-35.) These requests were denied *in toto*. [Expressly, with respect to A-35 (A-38-A-40); by silence with respect to A-41-A-48.]

Petitioner thereupon instituted the within suit, alleging in the second through fifth causes of action (each interrelated by the common contention that the Commission's rulemaking proceeding was beyond its authorized powers) that petitioner had been and would continue to be irreparably injured by the proceeding itself, irrespective of whether the proposed trade regulation rule would ever actually be promulgated or enforced against it. The complaint sought relief by way of injunction and declaration, the basis for jurisdiction in the district court being sections 3 and 10 of the Administrative Procedure Act (5 U.S.C. §§ 1002, 1009, now 5 U.S.C. §§ 552, 704), the Declaratory Judgment Act (28 U.S.C. § 2201) and 28 U.S.C. § 1337 (A-4).

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[2] Allegations in the complaint must be deemed admitted as the judgment of which review is sought was rendered on a motion to dismiss the complaint for failure to state a claim as a matter of law. In any event, the government's affidavits submitted in support of an alternative motion for summary judgment do not controvert any of the material factual allegations of the complaint.

The Commission moved to dismiss the complaint or, alternatively, for summary judgment (A-52-A-53). The district court granted the motion to dismiss, ruling (without deciding the merits of this aspect of the case) that petitioner's judicial challenge of the rulemaking proceeding was premature (Appendix I, *infra*, pages 5a-6a). The Court of Appeals affirmed, again not on the ground that the Commission's rulemaking procedure was within its authorized power, but that petitioner's claim to the contrary was "not yet ripe for adjudication" (Appendix I, *infra*, page 14a).

Reasons for Allowance of Writ

Trade regulation rules, if valid, would be strong medicine. They would empower the Commission to issue cease and desist orders under FTCA [3] § 5(b) without supporting its burden of proof with substantial evidence, and without extending to the private party the usual rights of procedural due process, many of which are explicitly restated in the APA,[4] especially §§ 7(d) and (e), 5 U.S.C. §§ 556(d) and (e).

Beyond that, trade regulation rulemaking would empower the Commission to make law in a legislative sense by the enactment of substantive regulations.

In the instant case, for example, the proposed rule would establish, by declaration and without the process of a trial, the unproven fact "that each of the various analgesic products now offered to the consuming public is effective to essentially the same degree as all other competing products supplying an equivalent quantity of an analgesic ingredient or combination of ingredients" (28a). Then, leaping from that premise, the rule would prohibit, as a matter

[3] Federal Trade Commission Act.

[4] Administrative Procedure Act.

of law, representations that violate its assumption (29a-30a).

Similarly, as pointed out at page 4 above, it would by proclamation "establish", without proving in an adjudicative proceeding as FTCA § 5(b) requires, that a number of specified advertising claims violate FTCA § 5(a), either without regard to whether they are in fact unfair and deceptive, or upon bare assumption that they are.

Thus, the trade regulation rule would be for the Commission a summary device for issuing cease and desist orders under FTCA § 5(b) without having to sustain its burden of proving litigatively that the target practices actually are unfair or deceptive.

Into the discard would go rights to which petitioner is entitled under principles of procedural due process and by various provisions of the FTCA and APA.[5] Thus, it would lose its opportunity to confront and cross-examine adverse witnesses; to conduct pre-trial discovery; to have subpoenas for compelling the presence of witnesses and the production of evidence. It would lose the protection of rules of evidence for promoting orderliness, fairness, and due process. It would no longer be protected by insulation of the hearing examiner and the Commissioners from all *ex parte* contacts which might influence their decisions, particularly those of Commission officers, employees or agents engaged in any related investigative or prosecuting functions.

Of major importance, in the same vein, is the factor that the trade regulation rule would transform the burden statutorily placed upon the Commission of proving unfairness or deception into one upon this petitioner to disprove it: first, by allowing the Commission to substitute the

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[5] FTCA §§ 5(b), 9, 15 U.S.C. §§ 45(b), 49; APA §§ 5(d), 6(d), 7(e)(2)(4), 7(d) and 7(e), 5 U.S.C. §§ 554(d), 555(d), 556(c)(2)(4), 556(d) and 556(e).

ipse dixit of its own rule in place of competent, substantial evidence to satisfy the burden; second, by declaring the petitioner vulnerable to a cease and desist order for making certain advertising claims unless *it* has established and can demonstrate that they are *not* deceptive,—with no apparent burden upon the Commission to prove that they are.[6]

The Commission evidently intends to make liberal use of this short-circuiting procedural weapon. It has, for example, undertaken proceedings to promulgate trade regulation rules to be used as the basis for § 5(b) cease and desist orders against marketers of gasoline who do not affirmatively post upon their gasoline pumps the octane ratings of the gasoline they dispense (34 Fed. Reg. 12449-50, July 30, 1969); and against marketers of household electric incandescent light bulbs who do not display on such bulbs, and their sleeves or paper containers, the light output, the life, and the electrical energy consumption of such bulbs in parameters prescribed in the proposed rule (34 Fed. Reg. 12528-9, July 31, 1969); and against vendors of textile products who do not permanently affix thereto a catalog of information for their proposed care in laun-

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[6] Proposed § 415.1(b) of the analgesic rule would prohibit representations ". . . that any analgesic effects resulting from the use of such product are faster, stronger, or longer lasting than those achieved by the use of a competitive product *unless the advertiser has established and can demonstrate* that a significant difference in such effects exists due to an increased total quantity of analgesic ingredient(s) in the recommended dosage, and this fact is clearly and conspicuously disclosed in the advertisement . . ."

§ 415.1(c)(2) would prohibit representations ". . . that any benefits will be derived from the action of any specified ingredient or combination of ingredients *unless . . . the advertiser has established and can demonstrate* that each such ingredient or combination of ingredients is efficacious as represented for the purpose for which it is offered when the product is taken in accordance with directions for use." (29a-30a; emphasis supplied.)

dering or cleaning (34 Fed. Reg. 17776 *et seq.*, November 4, 1969).[7]

The question of law petitioner seeks to present is not, of course, whether the objectives of such rules are desirable or not, but whether it lies within the authorized power of the Commission to achieve them, in the manner it has undertaken, rather than within the congressional province.

Clearly, the implicit premise of such proposed rules, like that of the proposed analgesic rule, must be either (1) that the practice (or non-practice) which the Commission intends to regulate by cease and desist order under § 5(b) is factually unfair or deceptive, or (2) that the Commission will treat it as though it were even if it is not.

Petitioner respectfully submits that it lies beyond the power of the Commission to issue a cease and desist order pursuant to § 5(b) unless: (1) It has performed the necessary fact-finding functions in conformance with that section, as well as with the relevant provisions of the APA referred to above, and with fundamental requirements of procedural due process; and (2) it has reached the necessary legal conclusions in conformance with valid principles of the applicable body of substantive law.

The Commission is not authorized to sidestep those vital prerequisites by simply making its own declaration as to what either the facts or the law, or both, shall be.

With no intent to argue here the merits of its claim that the Commission is unauthorized to exercise the power, which it purports to assert under § 1.12 of its rules, to

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[7] The Chairman of the Federal Trade Commission, Hon. Casper W. Weinberger, in his address before the Antitrust Section of the American Bar Association on April 9, 1970, commented, "Not least of [the Commission's positive] achievements was the development of the trade regulation rule as a vehicle for broad scale enforcement and across the board guidance".

promulgate substantive regulations, but merely to indicate that petitioner's contention to that effect is not without substance, it offers one concise, certainly not exhaustive, reference: Shapiro, *The Choice of Rulemaking or Adjudication in the Development of Administrative Policy*, 78 Harv. L. Rev. 921, 960-961 (Mar. 1965).[8]

If petitioner is correct in its contentions, then, it respectfully submits, an earliest possible definitive adjudication to that effect is of considerable importance in light of the Commission's apparent intention to make substan-

[8] Especially:

"In several crucial areas of administration, no grant of authority to issue prescriptive regulations in the sense used here is to be found. Two noteworthy examples relate to the powers of the NLRB and FTC: with a few exceptions relating to particular subjects, neither agency has express authority to give content to the general statutory prohibitions by promulgating regulations requiring certain acts to be performed or declaring specific acts or practices to be unlawful. Instead, each is vested only with general powers to issue such rules and regulations as may be necessary to carry out the provisions of the statute. At least in the case of FTC, the omission was not inadvertent. A proposal to give the FTC authority to issue regulations 'defining more' particularly unfair trade practices or unfair or oppressive competition' was not adopted by the committee that recommended enactment of the Federal Trade Commission Act in 1914; similar proposals were rejected on the floor; and it was stressed during the debates that the Commission would 'not be exercising power of a legislative nature.' [See H.R. Rep. No. 533, 63d Cong., 2d Sess., pt. 3, at 21 (1914); 51 Cong. Rec. 9047, 9049-50, 9056-57, 14932, 14938 (1914).] * * * Several observers have indicated that the general grant of authority to issue regulations may be far narrower in scope, being confined essentially to matters of interpretation, procedure, and internal organization. [H.R. Rep. No. 3236, 81st Cong., 2d Sess. 31 (1951); Att'y Gen. Comm. on Administrative Procedure, Final Report 98 n. 18 (1941); Hart, The Exercise of Rule-Making Power, in President's Comm. on Administrative Management, Report 309, 332 (1937).]"

tial use of the unauthorized procedure to regulate many important matters in many important industries. Since the question of the Commission's authority to issue rules with the imputed effect of § 1.12 is purely a legal one (*supra*, pages 2, 10), this Court can immediately review that issue without the necessity of remand.[9]

In order to do so in this case, however, the Court must first pass upon petitioner's right to have such a review at this time; in other words, the ripeness point, upon which the courts below dismissed the causes of action that raise the issue.

Hence, petitioner requests issuance of a writ of certiorari to review the holding of the courts below that those causes of action are premature, so that this Court can then reach what is truly the important question of law, namely, validity of § 1.12 of the Commission's Rules of Practice and Procedure.

In substantiation of its right to immediate judicial review, petitioner, of course, cites 1) APA § 10(c), 5 U.S.C. § 704, as creating a statutory ripeness for judicial review of "final agency action", and 2) the immediate and irreparable injury caused it by the Commission's pursuit of

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[9] The holding in F.T.C. v. Fred Meyer, Inc., 390 U.S. 341, 88 S.Ct. 904, 19 L.Ed.2d 1222 (1968), rested upon a rule of law of first impression, which had not been raised or considered in the Court of Appeals, nor urged before the Supreme Court.

See also Kiefer-Stewart Co. v. Joseph E. Seagram & Sons, 340 U.S. 211, 214, 71 S.Ct. 259, 261, 95 L.Ed. 219 (1951):

> "Respondents also seek to support the judgment of reversal on other grounds not passed on by the Court of Appeals but which have been argued here both orally and in the briefs. These grounds raise only issues of law not calling for examination or appraisal of evidence and we will consider them."

public proceedings to promulgate the unauthorized regulation, even if no sanction is ever imposed upon petitioner as a result thereof.[10] (*Supra*, pages 5-6.)

Conclusion

For the foregoing reasons, this petition for a writ of certiorari should be granted.

Respectfully submitted,

GILBERT H. WEIL,
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Of Counsel:
WEIL, LEE & BERGIN,
MELVILLE EHRLICH

June, 1970

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[10] Abbott Laboratories v. Gardner, 387 U.S. 136, 153, 87 S.Ct. 1507, 1518, 18 L.Ed. 2d 681 (1967):

> "It is relevant at this juncture to recognize that petitioners deal in a sensitive industry, in which public confidence in their drug products is especially important. To require them to challenge these regulations only as a defense to an action brought by the Government might harm them severely and unnecessarily."

Jenkins v. McKeithen, 395 U.S. 411, 424-425, 89 S.Ct. 1843, 1850, 23 L.Ed. 2d 404 (1969):

> "It is no answer that the Commission has not itself tried to impose any direct sanctions on appellant; it is enough that the Commission's alleged actions will have a substantial impact on him. * * * Finally, in the circumstances of the present case, we do not regard appellant's opportunity to defend any criminal prosecutions as sufficient to deprive him of standing to challenge the Act."

APPENDIX I

Opinion of District Court

UNITED STATES DISTRICT COURT

FOR THE DISTRICT OF COLUMBIA

Civil Action No. 2905-67

BRISTOL-MYERS COMPANY,

Plaintiff,

against

FEDERAL TRADE COMMISSION, *et al.*,

Defendants.

GILBERT H. WEIL, of New York, N. Y., for the plaintiff.

MICHAEL R. LEMOV, Department of Jusice, and ERNEST G. BARNES, Federal Trade Commission, both of Washington, D. C., for the defendants.

This is a motion by the Federal Trade Commission to dismiss a complaint in an action brought against it by a manufacturer of medicines. The complaint contains a number of counts and has several distinct aspects. In fact, these distinct aspects could have been brought as separate actions, although under the Federal Rules of Civil Procedure consolidation of claims is encouraged.

The first claim is one for a disclosure of certain records of the Federal Trade Commission. The plaintiff bases its rights on the recent statute enacted on June 5, 1967, 81 Stat. 54, 5 U.S.C. § 552, which requires Government agencies to disclose certain records to members of the public. The plaintiff is interested in a rule-making pro-

ceeding that has been instituted by the Federal Trade Commission and is now pending before it, in (2) regard to certain types of medicines. The object of these medicines is to diminish pain. The plaintiff is a manufacturer of some of them.

In connection with this proceeding the plaintiff served a demand upon the Commission, which it entitled a Petition, and in which it requested the Commission to identify to the petitioner in writing each item of material, whatever its form or nature, which relates to, bears upon, contains or purports to describe, report or discuss, or which otherwise, in whole or in part, records, reflects, evidences, has contributed to or constitutes: (a) information concerning the speed, strength, and duration of effect of certain medicines; (b) information concerning the extent to which any benefit is claimed to be derived from such medicines; (c) the extensive staff investigation alleged to have been made by the Commission, its accumulated experience and available studies and reports concerning the subject matter. The breadth of that demand is readily visible from merely reading it.

The demand then continues to request copies of any of the items previously mentioned that are within the possession or control of the Commission. It requests a specification of the names, addresses of firms or agencies that have custody, possession or control of any document which is not being furnished. This demand was not complied with. This action seeks an order of this Court to require compliance.

To determine the rights of the parties we must turn to the applicable statute, 5 U.S.C. § 552. It is a recent enactment and it has received very little judicial construction. Paragraph (a)(3) of that statute requires every Federal agency, on request for identifiable records, to make them available to any person. The statute continues to confer upon the District Courts the power to enforce this provision.

(3) Manifestly, it was not the purpose of Congress to permit any person whatever to roam at will within the files of every Government agency. Such a result would not only disrupt the day-to-day business of every Government agency, because a large percentage of the personnel of the Government would be occupied by furnishing information and copies of documents, but it would also harmfully affect the affairs of the Government and the interests of the citizens of the United States. Surely it was not intended that files relating to national defense or the foreign policy of the United States should be available to any person for the asking, even if he is an alien, because this statute is not limited to citizens. Surely it was not intended that any person could require access to the personnel records of somebody in whom he might be interested either favorably or adversely. Such a result would unnecessarily embarrass many Government employees and applicants for employment. Surely it was not intended that by this means a business concern could get at the secrets of its competitors that may be found in the files of some department.

Like all statutes, this Act must be reasonably construed. Its purpose was to prevent Government agencies from unjustifiably withholding information that should be reasonably available to a person having some basis for seeking it. That this must have been the intent of Congress appears, first, from the rather limited grant of power. It is granted only as to identifiable records. Secondly, it appears from the exceptions, which are almost greater than the grant.

An identifiable record necessarily means a record that is described with sufficient precision in order that by ministerial action of some subordinate the document can be identified and selected out of the files. It does not mean that the head (4) of an agency or his immediate assistant

must use judgment in seeking through the file to determine whether a particular document is within the classification asked for. That would be an unreasonable request.

Failure to comply with an order of the Court may be punishable as a contempt. In order that an act may be so punishable it must be defined with precision in order that a person who may be punished knows in advance what he must do and what he does not have to do. The demand in the case at bar is not confined to requesting access to particular documents. It does much more. It asks the Federal Trade Commission to prepare a list, after going through the files, of documents falling within certain classifications. There is no such requirement in the statute.

This is one side of the coin, so to speak. Now let us look at the negative provisions, namely, the exceptions. First, it is provided in sub-section (b) that the statute does not apply to an enumerated series of matters. Paragraph (b) (4) lists trade secrets and commercial or financial information obtained from a person and privileged or confidential. In the course of its investigations the Federal Trade Commission frequently obtains information from persons engaged in manufacture or commerce, information of a type that these persons do not wish to have disclosed to their competitiors. The blanket and dragnet demand involved in this action covers many such items.

Paragraph (b)(7) contains an exception for investigatory files compiled for law enforcement purposes. Law enforcement is not limited to enforcement of the criminal law, as was recently held by Judge Morgan of the Northern District of Georgia, in *Clement Brothers Co., Inc.* v. *National Labor Relations Board,* Civil Action 11174, decided February 6, 1968, not yet reported. (5) The demand involved in this case comprises numerous files that come within the exception just referred to, namely, investigatory files compiled for law enforcement purposes.

Still another exception is for inter-agency or intra-agency memoranda or letters, which would not be available by law to a party other than an agency in litigation with the agency. Every Government department, just as any large private concern, contains in its files memoranda from one member of its personnel to another. A subordinate may write to his chief advising a certain course of action. That recommendation may be overruled by the chief. Such memoranda are not subject to disclosure. If they were, members of the staff of Government departments would hesitate to communicate with each other. The demand in this action is broad enough to comprise many items of this type.

For all of these reasons it is clear that the demand made in this case is far too broad, and far too general, and calls for documents to be furnished and things to be done not contemplated within the statute. The Federal Trade Commission should not be put to the burden of selecting those matters which are properly subject to disclosure out of the vast morass of material that obviously is not subject to the provisions of the Act.

Accordingly, the Court is of the opinion that the plaintiff is not entitled to relief on this aspect of its complaint.

The second aspect consists of a request for an injunction against the rule-making proceeding which is now pending. It is claimed in behalf of the plaintiff that the type of rule that is contemplated and that was tentatively promulgated by the Commission for comment by interested parties, is not within the power of the Commission to enact. The Federal Trade Commission, (6) like other Government agencies, has rule-making power. The U. S. Code, Title 15, Section 46(g), expressly authorizes the Commission to make rules and regulations for the purpose of carrying out the provisions of the Act.

However, it is argued that the Commission is not clothed with power to conduct rule-making proceedings but may

conduct only adjudicatory proceedings, 15 U.S.C. § 45(b), and that, therefore, the proceeding that has been instituted for the purpose of promulgating a general rule regulating certain aspects of commerce in medicines is not within the power of the Commission. On this aspect of the case the Court is of the opinion that the action is premature. It is a well established rule of law that the courts will not interfere with administrative proceedings while they are pending. As a matter of fact, no one can tell today what type of rule, if any, will eventually be adopted by the Commission. When one is adopted, if it is adopted at all, will be the proper time to seek court review.

Finally, it is sought to enjoin the Commission from issuing what are popularly known as press releases that may be injurious to plaintiff and other manfuacturers of drugs. A so-called press release is nothing but a statement. The courts may no more enjoin Government departments from issuing statements to the public any more than they can enjoin a public official from making a speech. As a matter of good morals, a Government agency ought not to prejudice any person by issuing statements concerning matters that are pending before it. This is, however, a question of morals or manners, rather than of legal rights or duties.

Then, finally, the plaintiff asks authority to take the depositions of various persons in connection with the rule-making proceeding before the Commission. This Court knows of no authority, either under the Federal Rules of Civil Procedure, or (7) under any statute, permitting such a procedure.

For all of these reasons the motion to dismiss the complaint is granted.

ALEXANDER HOLTZOFF
United States District Judge

May 24, 1968.

Order of District Court

UNITED STATES DISTRICT COURT

DISTRICT OF COLUMBIA

Civil Action No. 2905-67

BRISTOL-MYERS COMPANY,

Plaintiff,

against

FEDERAL TRADE COMMISSION, *et al.*,

Defendants.

This cause having come on to be heard, on May 24, 1967, on the motion of defendants to dismiss the action, or in the alternative for summary judgment; and the Court having considered said motion, the memoranda and affidavits of plaintiff and defendants in support of, and opposition thereto and all of the previous pleadings filed in this action and the Court having heard argument by counsel for plaintiff and defendants in open court, it is this 11 day of June 1968,

ORDERED that plaintiff's First Cause of Action seeking production of records pursuant to the Administrative Procedure Act is hereby dismissed; and it is,

ORDERED that plaintiff's Second Cause of Action, seeking discovery in the Federal Trade Commission's pending analgesic rule-making proceeding is hereby dismissed for failure to state a claim upon which relief can be granted, and, it is,

Order of District Court

ORDERED that plaintiff's Third Cause of Action, seeking to enjoin issuance by the Federal Trade Commission of news releases with respect to the aforesaid proceeding is hereby dismissed for failure to state a claim upon which relief can be granted, and, it is,

ORDERED that plaintiff's Fourth and Fifth Causes of Action seeking to enjoin the Federal Trade Commission from proceeding with its pending analgesic rule-making proceeding are hereby dismissed as premature, and it is

FURTHER ORDERED that this action is hereby dismissed.

ALEXANDER HOLTZOFF
United States District Judge

Opinion of Court of Appeals

UNITED STATES COURT OF APPEALS

FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 22,277

BRISTOL-MYERS COMPANY, APPELLANT

v.

FEDERAL TRADE COMMISSION, *et al.*

APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

Decided March 26, 1970

Mr. Gilbert H. Weil, with whom *Mr. Melville Ehrlich* was on the brief, for appellant.

Mr. Leonard Schaitman, Attorney, Department of Justice, with whom *Messrs. David G. Bress,* United States Attorney at the time the brief was filed, and *Morton Hollander,* Attorney, Department of Justice, were on the brief, for appellee.

Before BAZELON, *Chief Judge,* WILBUR K. MILLER, *Senior Circuit Judge* and MACKINNON, *Circuit Judge.*

BAZELON, *Chief Judge*: This is a case requiring us to construe the Freedom of Information Act.[1] The Bristol-(2) Myers Company seeks an order compelling the Federal Trade Commission to produce certain documents relevant to a rulemaking proceeding initiated by the Commission

[1] 5 U.S.C. § 552 (Supp. IV, 1969).

on the basis of "extensive staff investigation, . . . accumulated experience and available studies and reports . . . ."[2] The Commission refused to produce the documents, and the District Court dismissed the complaint, ruling that the material sought did not constitute "identifiable records" whose production is required by statute, and furthermore that many of the documents sought fell within the statutory exemptions for trade secrets, internal agency documents, or investigatory files compiled for law enforcement purposes.[3] We reverse and remand for specific rulings on the various items requested.

I

The legislative history establishes that the primary purpose of the Freedom of Information Act was to increase the citizen's access to government records.[4] Before 1967, the Administrative Procedure Act contained a Public Information section "full of loopholes which allow[ed] agencies to deny legitimate information to the public."[5] When Congress acted to close those loopholes, it clearly intended to avoid creating new ones. The statutory requirement that a request for disclosure specify "identifiable records" calls for "a reasonable description enabling the Government employee to locate the requested records," but it is "not to be (3) used as a method of withholding records."[6] The F.T.C.

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[2] 32 Fed. Reg. 9843 (July 6, 1967).

[3] Bristol-Myers Company v. F.T.C., 284 F. Supp. 745 (D.D.C. 1968).

[4] American Mail Line, Ltd. v. Gulick, — U.S. App. D.C. —, —, 411 F.2d 696, 699 (1969).

[5] S. Rep. No. 813, 89th Cong., 1st Sess. 3 (1965); *see* H. R. Rep. No. 1497, 89th Cong., 2d Sess. 5 (1966).

[6] S. Rep. No. 813, *supra* note 5, at 8; *see Attorney General's Memorandum on the Public Information Section of the Administrative Procedure Act* 24 (1967).

can hardly claim that it was unable to ascertain which documents were sought by Bristol-Myers . The Commission relied on certain materials in promulgating its proposed rule, and referred to them in announcing the rulemaking proceeding. These materials are adequately identified in the request for disclosure of the items mentioned in the Commission's Notice.[7] To the extent that the request may be read as seeking additional material outside that category, the claim of failure to meet the identification requirement may be more plausible.[8] The company's request is clearly separable, however, and separate rulings are required.

Among the "identifiable records" sought by the company, there may well be some which are statutorily exempt from disclosure. The difficulty here is that the District Court failed to examine the disputed documents, and to explain the specific justification for withholding particular items. The legislative plan creates a liberal disclosure requirement, limited only by specific exemptions which are to be narrowly construed.[9] Each exemption cited by the District (4) Court raises substantial difficulties of interpretation, which cannot be resolved on the record before us.[10]

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[7] The petition filed by Bristol-Myers with the F.T.C. sought the identification and disclosure of "each item of material, whatever its form or nature, which . . . has contributed to or constitutes" the "extensive staff investigation," "accumulated experience," "available studies and reports," and "other things" referred to in the Commission's Notice.

[8] The petition also sought each item which has contributed to or constitutes information concerning the effect of any analgesic and information concerning the accuracy of appellant's assertions concerning the effects of various ingredients of its own analgesic products.

[9] 5 U.S.C. § 552(c) (Supp. IV, 1969).

[10] *See generally*, Note, *Freedom of Information: The Statute and The Regulations*, 56 GEO. L.J. 18 (1967); Davis, *The Information Act: A Preliminary Analysis*, 34 U. CHI. L. REV. 761 (1967).

The first exemption cited protects "trade secrets and commercial or financial information obtained from a person and privileged or confidential." 5 U.S.C. § 552(b)(4). This provision serves the important function of protecting the privacy and the competitive position of the citizen who offers information to assist government policy makers. Nevertheless, the statutory scheme does not permit a bare claim of confidentiality to immunize agency files from scrutiny. The District Court in the first instance has the responsibility of determining the validity and extent of the claim, and insuring that the exemption is strictly construed in light of the legislative intent. The court may well conclude that portions of the requested material are protected, and it may be that identifying details or secret matters can be deleted from a document to render it subject to disclosure.[11] These judgments are possible only after careful consideration of the particular documents in question, and it is for this detailed analysis that we remand.

A similarly detailed analysis is necessary in connection with each of the other exemptions cited by the District Court. The statute exempts "inter-agency or intra-agency memorandums or letters which would not be available by law to a party other than an agency in litigation with the agency." 5 U.S.C. § 552(b)(5). This provision encourages the free exchange of ideas among government policy makers, but it does not authorize an agency to throw a pro-
(5) tective blanket over all information by casting it in the form of an internal memorandum. Purely factual reports and scientific studies cannot be cloaked in secrecy by an exemption designed to protect only "those internal working papers in which opinions are expressed and policies

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[11] *See* Grumman Aircraft Engineering Corp. v. Renegotiation Board, — U.S. App. D.C. —, — F.2d — (No. 22,635, March 10, 1970).

formulated and recommended".[12] Furthermore, an internal memorandum may lose its protected status when it is publicly cited by an agency as the sole basis for agency action.[13] On remand, the District Court will have the opportunity to evaluate the content and status of those documents which the Commission would protect as internal memoranda.

Finally, the court cited the exemption for "investigatory files compiled for law enforcement purposes except to the extent available by law to a party other than the agency". 5 U.S.C. §552(b)(7). The threshold question here is whether the files sought by Bristol-Myers relate to anything that can fairly be characterized as an enforcement proceeding.

At one time the Commission apparently intended to deal with the subject of its proposed rule by proceeding against Bristol-Myers and other companies for misleading advertising practices.[14] Thus there is some basis for the view that the items sought are "investigatory files compiled for law enforcement purposes". Nevertheless, the complaint was withdrawn more than two years prior to the Notice of Rulemaking that precipitated the company's present re- (6) quest for documents. If further adjudicatory proceedings are imminent, then the company's request may fall within the category the exemption was designed to control. Congress intended to limit persons charged with violations of the federal regulatory statutes to the discovery available to

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[12] Ackerly v. Ley, — U.S. App. D.C. —, —, — F.2d —, — (No. 22,665, Dec. 19, 1969) (slip op. at 8); *accord*, General Services Admin. v. Benson, 415 F.2d 878, 880-81 (9th Cir. 1969); *see also* Boeing Airplane Co. v. Coggeshall, 108 U.S. App. D.C. 106, 280 F.2d 654 (1960).

[13] American Mail Line, Ltd. v. Gulick, *supra* note 4, at —, 411 F.2d at 703.

[14] *See* Bristol-Myers Co., F.T.C. Docket No. 8319 (complaint withdrawn, April 7, 1965).

persons charged with violations of federal criminal law.[15] The exemption prevents a litigant from using the statute to achieve indirectly "any earlier or greater access to investigatory files than he would have directly . . ."[16] But the agency cannot, consistent with the broad disclosure mandate of the Act, protect all its files with the label "investigatory" and a suggestion that enforcement proceedings may be launched at some unspecified future date. Thus the District Court must determine whether the prospect of enforcement proceedings is concrete enough to bring into operation the exemption for investigatory files, and if so whether the particular documents sought by the company are nevertheless discoverable.

II

Appellant's remaining claims require little discussion. Bristol-Myers seeks to enjoin the F.T.C. from continuing its rulemaking proceeding, either pending production of the requested documents, or permanently, on the ground that the Commission has no statutory or constitutional authority to promulgate its proposed rule. We affirm the District Court's holding that the claim for permanent injunctive relief is not yet ripe for adjudication. The Commission has merely proposed a rule, which may never be adopted or enforced. Even after a rule has been promulgated, the ripeness doctrine may in some circumstances bar judicial review prior to actual enforcement.[17] The rule-making au- (7) thority of an agency cannot usually be fairly tested in the absence of a specific legal and factual setting.

The request for temporary injunctive relief is likewise premature. If the District Court finds that the Commission

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[15] Barceloneta Shoe Corp. v. Compton, 271 F.Supp. 591, 593 (D.P.R. 1967).

[16] H. R. REP. NO. 1497, *supra* note 5, at 11.

[17] *Compare* Toilet Goods Ass'n v. Gardner, 387 U.S. 158 (1967) *with* Gardner v. Toilet Goods Ass'n, 387 U.S. 167 (1967) *and* Abbott Laboratories v. Gardner, 387 U.S. 136 (1967).

is improperly withholding documents, then the court is empowered to order production, and to enforce that order by contempt proceedings if necessary.[18] No showing has been made that Bristol-Myers will suffer irreparable injury during the time required for that process. If there is substantial delay in determining appellant's right to disclosure, or in achieving such disclosure as the statute requires, the District Court may consider the propriety of granting temporary relief.

Finally appellant seeks to enjoin the Commission from publicizing its proposed rule or any relevant proceedings. The court below denied relief and we affirm. The F.T.C. is specifically authorized by statute to publicize information acquired by it.[19] In *F.T.C.* v. *Cinderella Career and Finishing Schools* [20] we interpreted the statute to authorize news releases concerning pending adjudicatory proceedings, reasoning that the benefit to the public outweighed any harm inflicted on the party to the proceedings. *A fortiori* publicity concerning proposed rulemaking must be within the contemplation of the statute, since in the case of rulemaking publicity confers similar benefits on the public, but the adverse impact on the industry is more diffuse. The rationale of *Cinderella* is equally applicable here, and the (8) injunction must be denied.[21]

With regard to production of records under the Freedom of Information Act, the order of the District Court is reversed and remanded for further proceedings consistent with this opinion. In all other respects the order is affirmed.

So ordered.

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[18] 5 U.S.C. § 552(a)(3) (Supp. IV, 1969).

[19] 15 U.S.C. § 46(f) (1964).

[20] 131 U.S. App. D.C. 331, 404 F.2d 1308 (1968).

[21] While we affirm the holding of the court below, we regret its broad dictum suggesting that an agency could never be enjoined from publicizing its activities. *See* B.C. Morton Int'l Corp. v. FDIC, 305 F.2d 692 (1st Cir. 1962).

Judgment of Court of Appeals

UNITED STATES COURT OF APPEALS

FOR THE DISTRICT OF COLUMBIA CIRCUIT

No. 22,277 September Term, 1969

Civil Action 2965-67

o

BRISTOL-MYERS COMPANY,

Appellant,

v.

FEDERAL TRADE COMMISSION, *et al.*

APPEAL FROM THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF COLUMBIA

o

Before: BAZELON, *Chief Judge*; WILBUR K. MILLER, *Senior Circuit Judge*; and MACKINNON, *Circuit Judge*.

This cause came on to be heard on the record on appeal from the United States District Court for the District of Columbia, and was argued by counsel.

ON CONSIDERATION THEREOF, it is ordered and adjudged by this Court that with regard to production of records under the Freedom of Information Act, the order of the District Court is hereby reversed, and this case is remanded to the District Court for further proceedings consistent with the opinion of this Court filed herein this date. In all other respects, the order of the District Court is affirmed.

Per Curiam

For the Court:

NATHAN J. PAULSON
Clerk

Dated: March 26, 1970

Opinion per Chief Judge Bazelon

APPENDIX II

Constitutional, Statutory and Rules Provisions Involved

UNITED STATES CONSTITUTION, AMENDMENT V:

> "No person shall * * * be deprived of life, liberty, or property, without due process of law; * * *."

FEDERAL TRADE COMMISSION ACT:

Section 5(a)(1), as amended, 66 Stat. 632 (1952), 15 U.S.C. § 45(a)(1):

> "Unfair methods of competition in commerce, and unfair or deceptive acts or practices in commerce, are declared unlawful."

Section 5(a)(6), as amended, 66 Stat. 632 (1952), 15 U.S.C. § 45(a)(6):

> "The Commission is empowered and directed to prevent persons, partnerships, or corporations, * * * from using unfair methods of competition in commerce and unfair or deceptive acts or practices in commerce."

Section 5(b), as amended, 52 Stat. 111 (1938), 15 U.S.C. § 45(b):

> "Whenever the Commission shall have reason to believe that any such person, partnership, or corporation has been or is using any unfair method of competition or unfair or deceptive act or practice in commerce, and if it shall appear to the Commission that a proceeding by it in respect thereof would be to the interest of the public, it shall issue and serve upon such person, partnership, or corporation a complaint stating its charges in that respect and containing a notice of a hearing upon

a day and at a place therein fixed at least thirty days after the service of said complaint. The person, partnership, or corporation so complained of shall have the right to appear at the place and time so fixed and show cause why an order should not be entered by the Commission requiring such person, partnership, or corporation to cease and desist from the violation of the law so charged in said complaint. * * * The testimony in any such proceeding shall be reduced to writing and filed in the office of the Commission. If upon such hearing the Commission shall be of the opinion that the method of competition or the act or practice in question is prohibited by sections 41-46 and 47-58 of this title, it shall make a report in writing in which it shall state its findings as to the facts and shall issue and cause to be served on such person, partnership or corporation an order requiring such person, partnership, or corporation to cease and desist from using such method of competition of such act or practice. * * *"

Section 6(g), 38 Stat. 721 (1914), 15 U.S.C. § 46(g):

"The commission shall also have power— * * *

From time to time to classify corporations and to make rules and regulations for the purpose of carrying out the provisions of Sections 41-46 and 47-58 of this title."

Section 9, 38 Stat. 722 (1914), 15 U.S.C. § 49:

"For the purposes of sections 41-46 and 47-58 of this title the commission, or its duly authorized agent or agents, shall at all reasonable times have access to, for the purpose of examination, and the right

to copy any documentary evidence of any corporation being investigated or proceeded against; and the commission shall have power to require by subpoena the attendance and testimony of witnesses and the production of all such documentary evidence relating to any matter under investigation.* * *

Such attendance of witnesses, and the production of such documentary evidence, may be required from any place in the United States, at any designated place of hearing.* * *

The commission may order testimony to be taken by deposition in any proceeding or investigation pending under said sections at any stage of such proceeding or investigation.* * * Any person may be compelled to appear and depose and to produce documentary evidence in the same manner as witnesses may be compelled to appear and testify and produce documentary evidence before the commission as hereinbefore provided.* * *"

ADMINISTRATIVE PROCEDURE ACT:

Section 2(4), 80 Stat. 381 (1966), 5 U.S.C. § 551(4):

"For the purpose of this subchapter—* * *

'rule' means the whole or a part of an agency statement of general or particular applicability and future effect designed to implement, interpret, or prescribe law or policy or describing the organization, procedure, or practice requirements of an agency. * * *."

Section 2(13), 80 Stat. 381 (1966), 5 U.S.C. § 551(13):

"For the purpose of this subchapter—* * *

'agency action' includes the whole or a part of an agency rule, order, license, sanction, relief, or the equivalent or denial thereof, or failure to act."

Constitutional, Statutory and Rules Provisions Involved

Section 4(b)(2), 80 Stat. 383 (1966), 5 U.S.C. § 553(b)(2):

> "General notice of proposed rule making shall be published in the Federal Register, * * * The notice shall include—. * * *
>
> reference to the legal authority under which the rule is proposed; * * * "

Section 5(d), 80 Stat. 384 (1966), 5 U.S.C. § 554(d):

> "The employee who presides at the reception of evidence pursuant to section 556 of this title shall make the recommended decision or initial decision required by section 557 of this title, unless he becomes unavailable to the agency. Except to the extent required for the disposition of ex parte matters as authorized by law, such an employee may not—
>
> (1) consult a person or party on a fact in issue, unless on notice and opportunity for all parties to participate; or
>
> (2) be responsible to or subject to the supervision or direction of an employee or agent engaged in the performance of investigative or prosecuting functions for an agency.
>
> An employee or agent engaged in the performance of investigative or prosecuting functions for an agency in a case may not, in that or a factually related case, participate or advise in the decision, recommended decision, or agency review pursuant to section 557 of this title, except as witness or counsel in public proceedings. * * * "

Constitutional, Statutory and Rules Provisions Involved

Section 6(b), 80 Stat. 385 (1966), 5 U.S.C. § 555(b):

> "* * * With due regard for the convenience and necessity of the parties or their representatives and within a reasonable time, each agency shall proceed to conclude a matter presented to it. * * *"

Section 6(d), 80 Stat. 385 (1966), 5 U.S.C. § 555(d):

> "Agency subpoenas authorized by law shall be issued to a party on request and, when required by rules of procedure, on a statement or showing of general relevance and reasonable scope of the evidence sought. * * *"

Section 7(c)(2)(4), 80 Stat. 386 (1966), 5 U.S.C. § 556(c)(2)(4):

> "Subject to published rules of the agency and within its powers, employees presiding at hearings may—* * *
>
> issue subpoenas authorized by law; * * *
>
> take depositions or have depositions taken when the ends of justice would be served; * * *"

Section 7(d), 80 Stat. 386 (1966), 5 U.S.C. § 556(d):

> "Except as otherwise provided by statute, the proponent of a rule or order has the burden of proof. * * * A sanction may not be imposed or rule or order issued except on consideration of the whole record. * * * and supported by and in accordance with the reliable, probative, and substantial evidence. A party is entitled to present his case or defense by oral or documentary evidence, to submit rebuttal evidence, and to conduct such cross-examination as

may be required for a full and true disclosure of the facts. * * * "

Section 7(e), 80 Stat. 386 (1966), 5 U.S.C. § 556(e):

"The transcript of testimony and exhibits, together with all papers and requests filed in the proceeding, constitutes the exclusive record for decision in accordance with section 557 of this title * * *. When an agency decision rests on official notice of a material fact not appearing in the evidence in the record, a party is entitled, on timely request, to an opportunity to show the contrary."

Section 10(c), 80 Stat. 392 (1966), 5 U.S.C. § 704:

"Agency action made reviewable by statute and final agency action for which there is no other adequate remedy in a court are subject to judicial review. * * * Except as otherwise expressly required by statute, agency action otherwise final is final for the purposes of this section whether or not there has been presented or determined an application for a declaratory order, for any form of reconsideration, or, unless the agency otherwise requires by rule and provides that the action meanwhile is inoperative, for an appeal to superior agency authority."

Section 12, 80 Stat. 388 (1966), 5 U.S.C. § 559:

"* * * Except as otherwise required by law, requirements or privileges relating to evidence or procedure apply equally to agencies and persons. Each agency is granted the authority necessary to comply with the requirements of this subchapter through the issuance of rules or otherwise. * * * "

Constitutional, Statutory and Rules Provisions Involved

DECLARATORY JUDGMENT ACT, 72 STAT. 349 (1958), 28 U.S.C. § 2201:

> "In a case of actual controversy within its jurisdiction, except with respect to Federal taxes, any court of the United States, upon the filing of an appropriate pleading, may declare the rights and other legal relations of any interested party seeking such declaration, whether or not further relief is or could be sought. Any such declaration shall have the force and effect of a final judgment or decree and shall be reviewable as such."

PROCEDURES AND RULES OF PRACTICE FOR THE FEDERAL TRADE COMMISSION.

Section 1.12, 16 C.F.R. § 1.12:

> "**Trade regulation rules.**
>
> (a) *Nature and authority.* For the purpose of carrying out the provisions of the statutes administered by it, the Commission is empowered to promulgate rules and regulations applicable to unlawful trade practices. Such rules and regulations (hereinafter called 'trade regulation rules') express the experience and judgment of the Commission, based on facts of which it has knowledge derived from studies, reports, investigations, hearings, and other proceedings, or within official notice, concerning the substantive requirements of the statutes which it administers.
>
> (b) *Scope.* Trade regulation rules may cover all applications of a particular statutory provision and may be nationwide in effect, or they may be limited to particular areas or industries or to particular product or geographic markets, as may be appropriate.
>
> (c) *Use of rules in adjudicative proceedings.* Where a trade regulation rule is relevant to any

issue involved in an adjudicative proceeding thereafter instituted, the Commission may rely upon the rule to resolve such issue, provided that the respondent shall have been given a fair hearing on the applicability to the rule to the particular case."

Section 3.31, 16 C.F.R. § 3.31:

"**Admissions as to facts and documents.**

(a) At any time after answer has been filed or after publication of notice of an adjudicative hearing in a rule-making proceeding under § 3.13, any party may serve upon any other party a written request for the admission of the genuineness of any relevant documents described therein, or the admission of the truth of any relevant matters of fact set forth in such request. * * * "

Section 3.32, 16 C.F.R. § 3.32:

"**Orders requiring access.**

Application for issuance of an order requiring any corporation being proceeded against to grant access to files for the purpose of examination and the right to copy documentary evidence shall be made in writing to the hearing examiner, and shall specify as exactly as possible the files to which access is requested, showing the general relevancy of the files and the reasonableness of the scope of the proposed order. * * * "

Section 3.33, 16 C.F.R. § 3.33:

"**Depositions.**

(a) *When justified.* At any time during the course of a proceeding, whether or not issue has been joined, the hearing examiner, in his discretion may order the taking of a deposition and the production of documents by the deponent. Such order may be entered upon a showing that the depo-

sition is necessary for purposes of discovery, and that such discovery could not be accomplished by voluntary methods. * * * "

Section 3.34, 16 C.F.R. § 3.34:

"**Subpoenas.**

(a) *Subpoenas ad testificandum.* Application for issuance of a subpoena requiring a person to appear and depose or testify at the taking of a deposition or at an adjudicative hearing shall be made to the hearing examiner.

(b) *Subpoenas duces tecum.* (1) Application for issuance of a subpoena requiring a person to appear and depose or testify and to produce specified documents, papers, books, or other physical exhibits at the taking of a deposition, or at a prehearing conference, or at an adjudicative hearing shall be made in writing to the hearing examiner, and shall specify as exactly as possible the material to be produced, showing the general relevancy of the material and the reasonableness of the scope of the subpoena. * * *

(2) Subpoena duces tecum may be used by any party for purposes of discovery or for obtaining documents, papers, books, or other physical exhibits for use in evidence, or for both purposes. When used for discovery purposes, a subpoena may require a person to produce and permit the inspection and copying of nonprivileged documents, papers, books, or other physical exhibits which constitute or contain evidence relevant to the subject matter involved and which are in the possession, custody, or control of such person."

Constitutional, Statutory and Rules Provisions Involved

Section 3.41(c), 16 C.F.R. § 3.41(c):

"General Rules. * * *

Rights of parties. Every party, except intervenors, whose rights are determined under § 3.14, shall have the right of due notice, cross-examination, presentation of evidence, objection, motion, argument, and all other rights essential to a fair hearing."

Section 3.42(f), 16 C.F.R. § 3.42(f):

"Presiding officials * * *

Interference. In the performance of their adjudicative functions, hearing examiners shall not be responsible to or subject to the supervision or direction of any officer, employee or agent engaged in the performance of investigative or prosecuting functions for the Commission, and all directions by the Commission to hearing examiners concerning any adjudicative proceeding shall appear in and be made a part of the record."

Sections 3.43(a), (b), 16 C.F.R. §§ 3.43(a), (b):

"Evidence.

(a) *Burden of proof.* Counsel representing the Commission, or any person who has filed objections sufficient to warrant the holding of an adjudicative hearing pursuant to § 3.13, shall have the burden of proof, but the proponent of any factual proposition shall be required to sustain the burden of proof with respect thereto.

(b) *Admissibility.* Relevant, material, and reliable evidence shall be admitted. Irrelevant, immaterial, unreliable, and unduly repetitious evidence shall be excluded. Immaterial or irrelevant parts of an admissible document shall be segregated and excluded so far as practicable."

Section 4.7, 16 C.F.R. § 4.7:

> **"Ex parte communications.**
>
> (a) In an adjudicative proceeding, no person not employed by the Commission, and no employee or agent of the Commission who performs any investigative or prosecuting function in connection with the proceeding, shall communicate ex parte, directly or indirectly, with any member of the Commission, or the hearing examiner, or any employee involved in the decisional process in such proceeding, with respect to the merits of that or a factually related proceeding.
>
> (b) In an adjudicative proceeding, no member of the Commission, hearing examiner, or employee involved in the decisional process of such proceeding, shall communicate ex parte, directly or indirectly, with any person not employed by the Commission, or with any employee or agent of the Commission who performs any investigative or prosecuting function in connection with the proceeding; with respect to the merits of that or a factually related proceeding. * * * "

32 Fed. Reg. 9843 (July 6, 1967):

> "ADVERTISING OF NONPRESCRIPTION SYSTEMIC ANALGESIC DRUGS
>
> NOTICE OF TRADE REGULATION RULEMAKING PROCEEDING
>
> Notice is hereby given that the Federal Trade Commission, pursuant to the Federal Trade Commission Act, as amended, 15 U.S.C. 41, et seq., and the provisions of Part I, Subpart B of the Commission's procedures and rules of practice, 32 F.R. 8444 (June 13, 1967), has ini-

tiated a proceeding for the promulgation of a Trade Regulation Rule regarding unfair and deceptive acts or practices in the advertising of nonprescription systemic analgesic drugs.

The Commission has initiated this proceeding, having reason to believe that manufacturers and other marketers of nonprescription systemic analgesic drug preparations, in the advertising of such products, have: (1) made representations with respect to the efficacy or safety thereof which contradict or exceed the warnings, statements or directions for use appearing on the label or in the labeling thereof; (2) falsely and deceptively represented that the analgesic effects resulting from the use of their products are faster, stronger, or longer lasting than those achieved by use of such competing products. (It appears that each of the various analgesic products now offered to the consuming public is effective to essentially the same degree as all other competing products supplying an equivalent quantity of an analgesic ingredient or combination of ingredients); (3) claimed that benefits will be derived from the action of a specified ingredient or combination of ingredients without disclosing the identity of such ingredient or combination of ingredients by its common or usual name(s); (4) claimed that benefits will be derived from the action of any specified ingredient or combination of ingredients without having established that each such ingredient or combination of ingredients is efficacious for the purpose for which it is offered when the product is taken in accordance with directions for use; and, therefore, that (5) these practices constitute an unfair method of competition and an unfair and deceptive act or practice, in violation of sections 5 and 12 of the Federal Trade Commission Act.

In taking this action the Commission has considered, among other things, the results of an extensive staff investigation of advertising representations for nonprescrip-

tion systemic analgesic drugs, and on the basis of its accumulated experience and available studies and reports, is of the opinion that the public interest in a Trade Regulation Rulemaking proceeding is specific and substantial.

Accordingly, the Commission therefore proposes the following Trade Regulation Rule:

§ 415.1. THE RULE.

In connection with the sale or offering for sale of nonprescription systemic analgesic drug preparations, subject to jurisdictional requirements of sections 5 and 12 of the Federal Trade Commission Act, it is an unfair method of competition and/or an unfair or deceptive act or practice to disseminate any advertisement which:

(a) Contains any representation with respect to efficacy or safety which contradicts, or in any manner exceeds, the warnings, statements or directions for use appearing on the label or in the labeling of such product; or

(b) Represents that any analgesic effects resulting from the use of such product are faster, stronger, or longer lasting than those achieved by the use of a competitive product unless the advertiser has established and can demonstrate that a significant difference in such effects exists due to an increased total quantity of analgesic ingredient(s) in the recommended dosage, and this fact is clearly and conspicuously disclosed in the advertisement; or

(c) Represents that any benefit will be derived from the action of any specified ingredient or combination of ingredients unless—

(1) The identity of such ingredient or combination of ingredients is clearly and conspicuously disclosed by its common or usual name(s), and,

(2) The advertiser has established and can demonstrate that each such ingredient or combination of ingredients is efficacious as represented for the purpose for which it is offered when the product is taken in accordance with directions for use.

For the purpose of carrying out the provisions of the statutes administered by it, the Commission is empowered to promulgate rules and regulations applicable to unlawful trade practices. Such Trade Regulation Rules express the experience and judgment of the Commission, based on facts of which it has knowledge derived from studies, reports, investigations, hearings, and other proceedings, or within official notice, concerning the substantive requirements of the statutes which it administers.

Where a Trade Regulation Rule is relevant to any issue involved in an adjudicative proceeding thereafter instituted, the Commission may rely upon the rule to resolve the issue, provided that the respondent shall have been given a fair hearing on the applicability of the rule to the particular case.

Protection of the consuming public from false, misleading, deceptive or unfair advertising of products, particularly those that may endanger human health or safety, is a prime duty of the Commission.

All interested persons, including the consuming public, are hereby notified that they may file written data, views, or arguments concerning the proposed Rule and the subject matter of this proceeding with Mr. Joseph W. Shea, Secretary, Federal Trade Commission, Sixth Street at Pennsylvania Avenue NW., Washington, D.C. 20580, not later than September 15, 1967. To the extent practicable, persons wishing to file written presentations in excess of two pages should submit 20 copies.

The data, views, or arguments presented with respect to the proposed rule will be available for examination by interested parties at the office of the Assistant Secretary for Legal and Public Records, Federal Trade Commission, Washington, D.C., and will be considered by the Commission.

All persons, firms, corporations, or others engaged in the sale or distribution of nonprescription analgesic drugs in commerce, as "commerce" is defined in the Federal Trade Commission Act, would be subject to the requirements of any Trade Regulation Rule promulgated in the course of this proceeding.

All interested parties, including the consuming public, are urged to express their approval or disapproval of the proposed rule, or to recommend revisions thereof, and to give a full statement of their views in connection therewith.

Issued: July 5, 1967.
By the Commission.

(SEAL)

JOSEPH W. SHEA,
Secretary."